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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6852]

Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc. et al.; Withdrawal of Approval of 111 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 111 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, Trang.Tran@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Table 1.

Application No.	Drug	Applicant
ANDA 040008	Heparin Sodium Injection USP, 1000 units/milliliter (mL)	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 040137	Chlorzoxazone Tablets USP, 500 milligrams (mg)	Do.
ANDA 040410	Methylphenidate Hydrochloride (HCl) Extended-Release Tablets USP, 20 mg	Do.
ANDA 040456	Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets, 1.25 mg/1.25 mg/1.25 mg/1.25 mg, 2.5 mg/2.5 mg/2.5 mg/2.5 mg, 5 mg/5 mg/5 mg/5 mg, and 7.5 mg/7.5 mg/7.5 mg/7.5 mg	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 040666	A-Hydrocort (hydrocortisone sodium succinate) for Injection USP, Equivalent to (EQ) 100 mg base/vial	Hospira, Inc., a Pfizer Company, 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 062520	Kanamycin Sulfate Injection, EQ 1 gram (g) base/3 mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062693	Cephradine for Oral Suspension USP, 125 mg/5 mL and 250 mg/5 mL	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 062844	Nafcillin for Injection USP, EQ 500 mg base/vial, EQ 1 g base/vial, EQ 1.5 g base/vial, EQ 2 g base/vial, and EQ 4 g base/vial	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062856	Oxacillin for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 g base/vial, EQ 2 g base/vial, and EQ 4 g base/vial	Do.
ANDA 062984	Oxacillin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package)	Do.
ANDA 062991	Penicillin G Potassium for Injection USP, 1 million	Do.

Application No.	Drug	Applicant
	units/vial, 5 million units/vial, 10 million units/vial, and 20 million units/vial	
ANDA 063008	Nafcillin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package)	Do.
ANDA 063014	Penicillin G Sodium for Injection USP, 5 million units/vial	Do.
ANDA 063106	Gentamicin Injection USP, EQ 40 mg base/mL	Teva Pharmaceuticals USA, Inc.
ANDA 064035	Cefuroxime for Injection USP, EQ 750 mg base/vial and EQ 1.5 g base/vial	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 065280	Cefazolin for Injection USP, EQ 500 mg base/vial and EQ 1 g base/vial	Cephazone Pharma, LLC, 250 E. Bonita Ave., Pomona, CA 91767
ANDA 065294	Ceftriaxone for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 g base/vial, and EQ 2 g base/vial	Do.
ANDA 065295	Cefazolin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package)	Do.
ANDA 065296	Cefazolin for Injection USP, EQ 20 g base/vial (Pharmacy Bulk Package)	Do.
ANDA 070301	Propranolol HCl and Hydrochlorothiazide Tablets USP, 40 mg/25 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070305	Propranolol HCl and Hydrochlorothiazide Tablets USP, 80 mg/25 mg	Do.
ANDA 070468	Verapamil HCl Tablets USP, 120 mg	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070549	Propranolol HCl Tablets USP, 20 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070703	Methyldopa Tablets USP, 250 mg	Do.
ANDA 070714	Haloperidol Injection USP, EQ 5 mg base/mL	Do.
ANDA 070851	Propranolol HCl and Hydrochlorothiazide Tablets USP, 40 mg/25 mg	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.

Application No.	Drug	Applicant
ANDA 070852	Propranolol HCl and Hydrochlorothiazide Tablets USP, 80 mg/25 mg	Do.
ANDA 070855	Verapamil HCl Tablets USP, 80 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070958	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/15 mg	Do.
ANDA 070959	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/25 mg	Do.
ANDA 070960	Methyldopa and Hydrochlorothiazide Tablets USP, 500 mg/50 mg	Do.
ANDA 071069	Methyldopa and Hydrochlorothiazide Tablets USP, 500 mg/30 mg	Do.
ANDA 071110	Lorazepam Tablets USP, 2 mg	Do.
ANDA 071117	Lorazepam Tablets USP, 0.5 mg	Do.
ANDA 071118	Lorazepam Tablets USP, 1 mg	Do.
ANDA 071485	Doxepin HCl Capsules USP, EQ 10 mg base	Do.
ANDA 071486	Doxepin HCl Capsules USP, EQ 25 mg base	Do.
ANDA 071666	Ibuprofen Tablets, 400 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 071792	Propranolol HCl Tablets USP, 90 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 071883	Betamethasone Valerate Lotion USP, EQ 0.1% base	Teva Pharmaceuticals USA, Inc.
ANDA 071919	Nalidixic Acid Tablets USP, 1 g	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 071936	Nalidixic Acid Tablets USP, 250 mg	Do.
ANDA 072061	Nalidixic Acid Tablets USP, 500 mg	Do.
ANDA 072164	Maprotiline HCl Tablets USP, 75 mg	Do.
ANDA 072795	Metaproterenol Sulfate Tablets USP, 20 mg	Do.

Application No.	Drug	Applicant
ANDA 072824	Baclofen Tablets USP, 10 mg	Do.
ANDA 073373	Morphine Sulfate Injection USP, 1 mg/2 mL (Ampule)	Do.
ANDA 073374	Morphine Sulfate Injection USP, 10 mg/10 mL (Ampule)	Do.
ANDA 073375	Morphine Sulfate Injection USP, 5 mg/10 mL (Vial)	Do.
ANDA 073376	Morphine Sulfate Injection USP, 10 mg/10 mL (Vial)	Do.
ANDA 073443	Meperidine HCl Injection USP, 10 mg/mL (Preservative Free)	Do.
ANDA 073444	Meperidine HCl Injection USP, 50 mg/mL	Do.
ANDA 073529	Doxapram HCl Injection USP, 20 mg/mL	Do.
ANDA 074032	Metoprolol Tartrate Injection USP, 1 mg/mL	Do.
ANDA 074195	Naproxen Sodium Tablets USP, EQ 250 mg base and EQ 500 mg base	Do.
ANDA 074276	Lorazepam Injection USP, 2 mg/mL and 4 mg/mL	Do.
ANDA 074279	Dobutamine Injection USP, EQ 12.5 mg base/mL	Do.
ANDA 074393	Isoflurane USP, 99.9%	Do.
ANDA 074457	Naproxen Tablets USP, 250 mg, 375 mg, and 500 mg	Do.
ANDA 074598	Hydromorphone HCl Injection USP, 10 mg/mL	Hospira, Inc.
ANDA 074864	Ranitidine Tablets USP, EQ 150 mg base and EQ 300 mg base	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074906	Acyclovir Capsules USP, 200 mg	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075253	Ticlopidine HCl Tablets, 250 mg	Do.
ANDA 075650	Famotidine Tablets USP, 20 mg and 40 mg	Do.
ANDA 075672	Bisoprolol Fumarate and Hydrochlorothiazide Tablets, 2.5 mg/6.25 mg, 5 mg/6.25 mg, and 10 mg/6.25 mg	Do.

Application No.	Drug	Applicant
ANDA 075843	Oxaprozin Tablets, 600 mg	Do.
ANDA 075901	Fluvoxamine Maleate Tablets, 25 mg, 50 mg, and 100 mg	Do.
ANDA 075960	Tramadol HCl Tablets, 50 mg	Do.
ANDA 076689	Mirtazapine Orally Disintegrating Tablets USP, 15 mg, 30 mg, and 45 mg	Do.
ANDA 077174	Foscarnet Sodium Injection, 2.4 g/100 mL	Hospira, Inc.
ANDA 077963	Granisetron HCl Injection, EQ 1 mg base/mL	Teva Pharmaceuticals USA, Inc.
ANDA 080615	Dimenhydrinate Injection, 50 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 080713	Tripeleannamine HCl Tablets USP, 50 mg	Do.
ANDA 081150	Hydroxyzine HCl Tablets USP, 25 mg	Do.
ANDA 081151	Hydroxyzine HCl Tablets USP, 50 mg	Do.
ANDA 083287	Procainamide HCl Capsules USP, 250 mg	Do.
ANDA 084280	Procainamide HCl Capsules USP, 500 mg	Do.
ANDA 084403	Procainamide HCl Capsules USP, 375 mg	Do.
ANDA 084467	Reserpine and Hydrochlorothiazide Tablets USP, 0.125 mg/50 mg	Do.
ANDA 085083	Diphenhydramine HCl Capsules USP, 50 mg	Do.
ANDA 085140	Quinidine Sulfate Tablets USP, 200 mg	Do.
ANDA 085173	Chlorothiazide Tablets USP, 250 mg	Do.
ANDA 085180	Methocarbamol Tablets USP, 500 mg	Do.
ANDA 085192	Methocarbamol Tablets USP, 750 mg	Do.
ANDA 085597	Methylprednisolone Acetate Injectable Suspension USP, 20 mg/mL	Do.
ANDA 086013	Statobex (phendimetrazine	Teva Pharmaceuticals USA, Inc.

Application No.	Drug	Applicant
	tartrate) Tablets USP, 35 mg	
ANDA 086029	Testosterone Cypionate Injection USP, 100 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 086031	Isosorbide Dinitrate Sublingual Tablets USP, 5 mg	Do.
ANDA 086034	Isosorbide Dinitrate Tablets USP, 5 mg	Do.
ANDA 086188	Gerimal (ergoloid mesylates) Sublingual Tablets, 1 mg	Do.
ANDA 086385	Nandrolone Decanoate Injection, 50 mg/mL	Do.
ANDA 086562	Wigraine (ergotamine tartrate and caffeine) Tablets USP, 1 mg/100 mg	Organon USA, Inc., Subsidiary of Merck & Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
ANDA 086742	Choledyl SA (oxtriphylline) Extended-Release Tablets, 600 mg	Warner Chilcott Co., LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 086863	Chlorpromazine HCl Oral Concentrate USP, 100 mg/mL	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 087233	Ergoloid Mesylates Sublingual Tablets USP, 0.5 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087244	Ergoloid Mesylates Tablets USP, 1 mg	Do.
ANDA 087318	Tolbutamide Tablets USP, 500 mg	Do.
ANDA 087727	Aminophylline Oral Solution USP, 105 mg/5 mL (Dye Free)	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088128	Nandrolone Decanoate Injection, 200 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088337	Ergostat (ergotamine tartrate) Sublingual Tablets USP, 2 mg	Do.
ANDA 088477	Thioridazine HCl Tablets USP, 15 mg	Do.
ANDA 088561	Thioridazine HCl Tablets USP, 10 mg	Do.

Application No.	Drug	Applicant
ANDA 088564	Thioridazine HCl Tablets USP, 100 mg	Do.
ANDA 088724	Methyclothiazide Tablets USP, 5 mg	Do.
ANDA 088734	Meclizine HCl Tablets, 25 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088769	Mepivacaine HCl Injection USP, 1%	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088770	Mepivacaine HCl Injection USP, 2%	Do.
ANDA 088872	Thioridazine HCl Tablets USP, 200 mg	Do.
ANDA 089026	Procainamide HCl Extended- Release Tablets USP, 250 mg	Do.
ANDA 089027	Procainamide HCl Extended- Release Tablets USP, 500 mg	Do.
ANDA 089530	Prochlorperazine Edisylate Injection USP, EQ 5 mg base/mL	Do.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see DATES) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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